

I applaud OHRP's work on this important and difficult issue. The attention to institutional conflicts of interest, IRB review and the consent process are important steps in developing agreement on best practices.

I strongly urge OPHR also to focus on the issue of university-based investigators in clinical trials holding stock, options, or a management position in the company manufacturing the product being tested (1). Such financial arrangements may be of greater concern than a recruitment bonus or finders' fee, which are discussed in 2.1. There is growing agreement that investigators with such arrangements at least should not be involved with patient selection, informed consent or clinical management of subjects (2, 3). Moreover, there is significant support for a total ban on stock and options for investigators in clinical trials. UCSF has such a ban, and the faculty agree that there is a significant difference between being paid a set amount for one's time and effort and having one's remuneration depend heavily (particularly in the case of start-up companies) on the outcome of the clinical trial. Several large cardiology trials have prohibited investigators from owning stock or options in the company whose product is being tested (4, 5). The American Federation for Clinical Research also supports such a ban (6).

References

1. Lo B, Wolf LE, Berkeley A. Conflict of interest policies for investigators in clinical trials. *N Engl J Med* 2001;343:1616-1620.
2. Policy of the American Society of Gene Therapy on financial conflict of interest in clinical research. *Molecular Therapy* 2000;1:384.
3. Friedmann T. Principles for human gene therapy studies. *Science* 2000;287:2163-2165.
4. Healy B, Campeau L, Gray R, et al. Conflict-of-interest guidelines for a multicenter clinical trial of treatment after coronary-artery bypass-graft surgery. *N Engl J Med* 1989;320:949-951.
5. Topol EJ, Armstrong P, Van de Werf F, et al. Confronting the issues of patient safety and investigator conflict of interest in an international trial of myocardial reperfusion. *J Am Coll Cardiol* 1992;19:1123-1128.
6. American Federation for Clinical Research guidelines for avoiding conflict of interest. *Clin Res* 1990;38:239-240.

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